**Highlighting the Benefits of Vegan Foods on the Label**

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Embracement of vegan diets is on the rise, but business reasonably could be elevated further by labeling vegan foods with a variety of nutritional claims for which they are eligible.

## BACKGROUND

The number of U.S. consumers adopting vegan diets has grown markedly over the past several years, spurred (in part) by notable role models, like Bill Clinton, Michelle Pfeiffer, and Carrie Underwood. Dietary vegans (a/k/a strict vegetarians) refrain from eating animal products -- not only meat, but (in contrast to other vegetarians) also eggs, dairy products, and other animal-derived foods (e.g., gelatin, honey).

Many vegans historically have adopted their lifestyles because they believe in animal rights, consistent with the views of Donald Watson, who coined the term "veganism" in 1944, defined as follows:

> Veganism is a way of living which excludes all forms of exploitation of, and cruelty to, the animal kingdom, and includes a reverence for life. It applies to the practice of living on the products of the plant kingdom to the exclusion of flesh, fish, fowl, eggs, honey, animal milk and its derivatives, and encourages the use of alternatives for all commodities derived wholly or in part from animals.

While veganism has this historical base, more recently the growing number of individuals adopting a vegan diet seems swayed by its impact on health. Even the present (i.e., 2010) Dietary Guidelines for Americans includes many references to vegan diets.

The Food and Drug Administration (FDA) regulates the labeling of packaged foods sold in the U.S., including vegan foods. The laws that FDA administers facilitate the marketing of vegan foods with label claims – including nutrient content claims, structure/function claims, and health claims -- that highlight their nutritional benefits and utility in promoting health.

## NUTRITIONAL CLAIMS

### 1. Nutrient Content Claims

A nutrient content claim expressly or implicitly characterizes the level of any nutrient in a packaged food. Nutrient content claims are authorized by, and must be used in accordance with, section 403(r) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (codified at 21 U.S.C. § 343(r)) and FDA's general (21 C.F.R. § 101.13) and specific, implementing regulations or other authorization.

An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food (e.g., "low sodium" or "contains 100 calories"). An implied nutrient content claim is any claim that (i) describes the food or an ingredient in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or (ii) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices (e.g., "healthy, contains 3 g of fat").

FDA has promulgated specific, implementing regulations that authorize nutrient content claims about:

- "Good source," "high," "more," "antioxidant," and "high potency" (to describe the level of potassium, dietary fiber, protein, vitamins, and/or minerals);
- "Light" or "lite"(to describe the level of calories, fat, and/or sodium);
- Calorie and sugars contents;
- Sodium and salt contents;
- Fat, fatty acid, and cholesterol contents; and
- Implied claims, including "healthy."

21 C.F.R. §§ 101.54, 101.56, 101.60, 101.61, 101.62, 101.65. Pursuant to notifications submitted under the FDA Modernization Act (FDAMA) of 1997, FDA also has authorized nutrient content claims for choline and linoleic acid in foods.

A statement about a nutrient not permitted to be listed in a packaged food's Nutrition Facts also may be made on the label as long as it specifies only the amount of the nutrient per serving and does not implicitly characterize the level of the nutrient in the product (e.g., "_ grams of omega-3 fatty acids"). 21 C.F.R. § 101.13(i)(3).

*See generally* Guidance for Industry: A Food Labeling Guide, 8. Claims at Questions and Answers (Q&A) N1-N49.

2. Structure/Function Claims

Structure/function claims are authorized for use on the label of packaged foods by FFDCA § 201(g)(1)(C) (codified at 21 U.S.C. § 321(g)(1)(C)). A structure/function claim describes the role of a dietary substance intended to affect a structure or function in humans (e.g., "calcium builds strong bones"), or characterizes the documented mechanism by which such a substance acts to maintain such a structure or function (e.g., "fiber maintains bowel regularity" or "antioxidants maintain cell integrity"). The dietary substance must have nutritive value, i.e., value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy. Unlike nutrient content claims and health claims, structure/function claims do not need to be authorized by FDA before they may be used in food labeling.

Examples of permissible structure/function claims include:

- For relief of occasional constipation;

- Helps support cartilage and joint function;
- Improves absentmindedness;
- Helps to maintain cholesterol levels that are already within the healthy range;
- Supportive for menopausal women;
- Use as part of your diet to help maintain a healthy blood sugar level;
- Supports the immune system;
- Helps maintain intestinal flora;
- Boosts stamina; and
- Digestive aid.

Structure/function claims must be supported by requisite scientific substantiation. *See generally* Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act (Dec. 2008) (note: while the guidance is for dietary supplements, it is applicable to conventional foods, as well).

A structure/function claim is *impermissible* if it is a disease claim. A "disease" is damage to an organ, part, structure, or system of the body, such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunction (e.g., hypertension); however, diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition. Ten (10) criteria that might be useful in determining whether a structure/function claim could be deemed a disease claim are discussed in Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide (Jan. 9, 2002) (note: while the guidance is for dietary supplements, it is applicable to conventional foods, as well).

3. Health Claims and Qualified Health Claims

A health claim characterizes the relationship of a dietary substance to a disease or health-related condition. Health claims are authorized by, and must be used in accordance with, FFDCA § 403(r) and FDA's general (21 C.F.R. § 101.14) and specific, implementing regulations or other authorization.

Health claims include any claim made on the label of a food that expressly or by implication -- including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes -- assert the existence of a relationship between a substance and a disease or health-related condition. The term "substance" means a specific food or component of food that includes vitamins, minerals, herbs, or other similar nutritional substances. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

FDA has promulgated specific, implementing regulations that authorize health claims about, for example:

- Dietary lipids and cancer;
- Sodium and hypertension;

- Dietary saturated fat and cholesterol and risk of coronary heart disease (CHD);
- Fiber-containing grain products, fruits, and vegetables and cancer;
- Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of CHD;
- Fruits and vegetables and cancer;
- Folate and neural tube defects;
- Soluble fiber from certain foods and risk of CHD;
- Soy protein and risk of CHD; and
- Plant sterol/stanol esters and risk of CHD.

21 C.F.R. §§ 101.73, 101.74, 101.75, 101.76, 101.77, 101.78, 101.79, 101.81, 101.82, 101.83. Pursuant to notifications submitted under FDAMA, FDA also has authorized health claims about, for example:

- Potassium and the Risk of High Blood Pressure and Stroke;
- Saturated Fat, Cholesterol, and *Trans* Fat, and the Risk of Heart Disease;
- Substitution of Saturated Fat with Unsaturated Fatty Acids and Risk of Heart Disease;
- Whole Grain Foods with Moderate Fat Content and the Risk of Heart Disease and Certain Cancers; and
- Whole Grain Foods and the Risk of Heart Disease and Certain Cancers.

Authorization of these health claims (i.e., unqualified) essentially required that "significant scientific agreement" underlie the health claim.

*See generally* Guidance for Industry: A Food Labeling Guide, 8. Claims at Q&A H1-H6.

In contrast, authorization to make a qualified health claim (QHC) on the label of a packaged food derives from litigation that raised First Amendment challenges to the "significant scientific agreement" standard. FDA in 2000 announced its intention to exercise its enforcement discretion with regard to certain categories of dietary supplement health claims that may not meet this standard. In 2002, FDA extended this approach to QHC on conventional foods. The assumption underlying this approach is that disclaimers will remedy any potential harm otherwise caused by potentially misleading claims. *See generally* Questions and Answers: Qualified Health Claims in Food Labeling: Draft Report on Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims (Sept. 28, 2005).

FDA has issued "letters of enforcement discretion" that essentially authorize a QHC about, for example:

- Tomatoes and Prostate, Ovarian, Gastric and Pancreatic Cancers;
- Green Tea and Risk of Breast Cancer and Prostate Cancer;
- Walnuts and CHD;
- Nuts and CHD;
- Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Disease;
- Unsaturated Fatty Acids from Canola Oil and Reduced Risk of CHD; and

- Monounsaturated Fatty Acids from Olive Oil and CHD.

RECOMMENDATION

A nutrient content claim, structure/function claim, and/or health claim/QHC made on the package label of a vegan food reasonably could promote its marketing by highlighting its benefits and distinguishing it from competitive products (i.e., conventional or alternative vegan foods).

The laws that FDA administers in regulating nutritional claims on food labels are intricate. Consultation with qualified counsel may be needed to ensure compliance.

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